

#28

Interview Summary

Application No.
09/454,740

Applicant(s)
Hillebrand et al.

Examiner
Arun Chakrabarti

Art Unit
1634

All participants (applicant, applicant's representative, PTO personnel):

(1) Arun Chakrabarti

(3) Ted Gottlieb

(2) Gary Jones

(4) TIMO HILEBRAND

Date of Interview Dec 2, 2002

(5) PETER BENDZKO

Type: a) ☐ Telephonic b) ☐ Video Conference
c) ☒ Personal [copy is given to 1) ☒ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No. If yes, brief description:

Claim(s) discussed: All

Identification of prior art discussed:

All

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Applicant was advised to clarify the basis in the specification especially of the phrase "antichainotropic salt at a concentration that allows binding of one or more of said nucleic acid" in the proposed amended claim. Applicant informed that they will provide 132 declaration to support their claim language. Applicant's declaration will be considered favorably. However, further consideration and search is necessary.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) ☒ It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Arun Kr. Chakrabarti
Examiner's signature, if required

NOTES FOR THE MEETING WITH EXAMINER A. CHAKRABARTI AND
SUPERVISORY EXAMINER G. JONES

Contents

- I. Proposed amendments to claim 1.
- II. Remarks.
 - A. Discussion related to the amendment
 - B. Discussion related to combining of the references.
- III. Mark up of amended claims.

I. PROPOSED CLAIM AMENDMENTS

1a. (Amended three times) A kit for isolating nucleic acids in the absence of chaotropic salt components by binding one or more nucleic acids to a substrate in the presence of at least one antichaotropic salt, the kit comprising

(a) a lysis/buffer system consisting essentially of

(i) the at least one antichaotropic salt present at a concentration that allows binding of said one or more nucleic acids to said substrate,

(ii) said substrate for binding said one or more nucleic acids ,

(iii) optionally, a wash buffer comprising at least 50% alcohol,

(iv) a low salt elution buffer, and

(v) optionally one or more detergent or additive chosen from the group

consisting of tris-HCl, EDTA, polyvinyl pyrrolidone, CTAB

(hexadecyltrimethylammonium bromide), Triton X-100, Nonidet-P40, n-lauryl

sarcosine, n- dodecylsulfate, sodium citrate, DTT, Brij ,Tween

(b) optionally enzymes; and

(c) optionally an alcohol for binding to the substrate.

II. REMARKS

A. Discussion Related to the Amendment

Applicants believe that both of the above proposed amended claims are allowable over cited references.

The amendment adds the feature requiring that the antichaotropic salt be present at a final concentration that allows nucleic acid binding to a substrate.

Adding this functional limitation overcomes the § 103(a) rejection because combining Anderson with **any or all** of the secondary references, does not teach or suggest all of the claim limitations. Accordingly, the rejection should be withdrawn.

This is because:

1. The added claim limitation is not met by Anderson alone or in combination with the secondary references. This is because Anderson's composition, as demonstrated therein, is not capable of allowing nucleic acid binding to a substrate. This was evidenced by the fact that the glass beads in his procedure do not bind to DNA. Thus, Anderson's disclosure, indisputably, lacks a component and/or an amount thereof, required to affect nucleic acid binding to a substrate. The secondary references do not cure this defect because they lack any disclosure or guidance as to how to promote nucleic

acid binding to a substrate in an antichaotropic environment. Thus, the added claim limitation is clearly not met by the combination of references.

2. Another reason that the combined references cannot render the amended claim obvious is that they disclose no teaching or suggestion as to which variable(s) could hypothetically be modified in order to affect nucleic acid binding to a substrate. Therefore, assuming *arguendo*, that Anderson's composition could be modified so that it could meet all of the claim limitations, the references provide no teaching or suggestions that would lead to such modifications.

The legal basis for this is derived from *In re Antonie* (195 USPQ 6, 8-9 (CCPA 1977)), where the CCPA held that such modifications cannot be *prima facie* obvious. Specifically, if one or more result-effective variable(s) in Anderson's composition could be modified to affect nucleic acid binding to a substrate, and that variable *is not recognized in the art as being result-effective*, then actually making the hypothetical modification cannot have been *prima facie* obvious.

In sum, absent the requisite teaching or guidance from the combined references that would lead persons with ordinary skill in the art to modify Anderson's composition, or that of another reference, the amendment overcomes the § 103(a) rejection over the references.

B. Combination of References

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983). In addition, “[i]t is improper to combine references where the references teach away from their combination.” *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983); MPEP§ 2145 – Consideration of Applicant’s Rebuttal Arguments.

With respect to the references cited in this application, Applicants respectfully point out that when taken in their entirety, the references teach away from their combination.

1. **Anderson in view of Cleuziat** – Anderson demonstrates that DNA does not bind to a substrate (glass beads) using his method and composition. Indeed, his buffer conditions are chosen specifically to avoid binding of DNA to the beads. The beads are present merely to aid in the mechanical disruption of the yeast cell walls.

Cleuziat discloses various substrates for binding DNA.

Applicants suggest that persons of ordinary skill would not reasonably be motivated to combines Anderson’s “non-binding” compositions and methods, with Cleuziat’s disclosed DNA-binding substrates. Respectfully, it appears that maintaining the rejection under § 103(a) over Anderson/Cleuziat is in clear violation of *Grasselli* and PTO guidelines.

Accordingly, Applicants respectfully request that the rejection be withdrawn in view

of this improper combination of references.

2. Anderson in view Nochumson — Anderson is cited for an alleged antichaotropic composition. Nochumson is cited for teaching a wash buffer having 50% alcohol and a low-salt elution buffer. However, when Nochumson is viewed in its entirety, Nochumson **expressly** teaches, *that binding of DNA to a substrate requires chaotropic ions.*

...it is **essential that the process be carried out in the presence of one or more chaotropic salts**,...and thus enhance the binding of DNA to the binding sites, including such salts as NaI, perchlorates, SCN⁻ salts and the like, but preferably NaI.

Nochumson, col. 11, lines 35-42; (Emphasis added).

Applicants respectfully suggest that given the antichaotropic nature of Anderson's buffer, combining it with the teachings of Nochumson also violates *Grasselli* and PTO guidelines.

Persons of ordinary skill would not be motivated to modify Anderson's antichaotropic composition by combining with the teachings of Nochumson, in view of the latter's express **requirement for chaotropic salts** in enhancing DNA binding to substrates.

The references cannot be combined because they teach away from each other.

III. MARK-UP OF PROPOSED AMENDED CLAIMS

1a. (Amended three times) A kit for isolating nucleic acids ~~from complex starting materials~~ in the absence of chaotropic salt components by binding one or more nucleic acid acids to a substrate in the presence of at least one antichaotropic salt, the kit comprising

a lysis/buffer system consisting essentially of

the at least one antichaotropic salt present at a concentration that allows binding of one or more said nucleic acids to said substrate means,

said substrate for binding DNA said one or more nucleic acids,

a wash buffer comprising at least 50% ethanol, and

a low salt elution buffer, and

optionally one or more detergent or additive chosen from the group consisting of tris-HCl, EDTA, polyvinyl pyrrolidone, CTAB (hexadecyltrimethylammonium bromide), ~~triton~~ Triton X-100, Nonidet-P40, n-lauryl sarcosine, n-dodecylsulfate, sodium citrate, DTT, Brij, Tween

optionally enzymes; and

optionally an alcohol for binding to the substrate means.